IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES, LTD.,	)	
Counterclaim Plaintiffs,	)	
v.	)	Civ. No. 02-1512-SLR (Consolidated)
ABBOTT LABORATORIES, FOURNIER INDUSTRIE ET SANTE and LABORATOIRES FOURNIER S.A.,	)	
Counterclaim Defendants.	)	
IMPAX LABORATORIES, INC.,	)	
Counterclaim Plaintiff,	)	
v.	)	Civ. No. 03-120-SLR (Consolidated)
ABBOTT LABORATORIES, FOURNIER INDUSTRIE ET SANTE and LABORATOIRES FOURNIER S.A.,	)	
Counterclaim Defendants.	)	
IN RE TRICOR DIRECT PURCHASER ANTITRUST LITIGATION	)	Civ. No. 05-340-SLR (Consolidated)
IN RE TRICOR INDIRECT PURCHASER ANTITRUST LITIGATION	)	Civ. No. 05-360-SLR (Consolidated)

Mary B. Matterer, Esquire of Morris James LLP, Wilmington, Delaware. Counsel for

Impax. Of Counsel: Robert A. Van Nest, Esquire, Mark A. Lemley, Esquire, Asim M. Bhansali, Esquire, and Paula L. Blizzard, Esquire of Keker & Van Nest, San Francisco, California; Philip J. McCabe of Kenyon & Kenyon, San Jose, California; C. Kyle Musgrove, Esquire of Kenyon & Kenyon, Washington, D.C.

Josy W. Ingersoll, Esquire, John W. Shaw, Esquire and Karen Elizabeth Keller, Esquire of Young, Conaway, Stargatt & Taylor, Wilmington, Delaware. Counsel for Teva Pharmaceuticals U.S.A., Inc., Teva Pharmaceuticals Industries Ltd. and Novopharm, Ltd. Of Counsel: David M. Hashmall, Esquire and Christopher T. HOlding, esquire of Goodwin Procter LLP, Boston, Massachusetts.

Elizabeth M. McGeever, Esquire of Prickett, Jones & Elliott, P.A., Wilmington, Delaware. Counsel for Walgreen Co., Eckerd Corporation, The Kroger Co., Maxi Drug, Inc. d/b/a Brooks Pharmacy, Albertson's, Inc., Safeway, Inc. and Hy-Vee, Inc., CVS Pharmacy, Inc., Rite Aid Corporation, Rite Aid Headquarters Corporation and American Sales Company, Inc.

Jeffrey S. Goddess, Esquire of Rosenthal, Monhait & Goddess, P.A., Wilmington, Delaware. Liason counsel for the direct purchaser class.

A. Zachary Naylor, Esquire of Chimicles & Tikellis LLP, Wilmington, Delaware. Liason counsel for the indirect purchaser class.

Jonathan L. Parshall, Esquire of Murphy & Landon, Wilmington, Delaware. Counsel for Pacificare Health Systems, Inc.

Mary B. Graham, Esquire and James W. Parrett, Jr., Esquire of Morris, Nichols, Arsht & Tunnell LLP, Wilmington, Delaware. Counsel for Abbott Laboratories. Of Counsel: William F. Cavanaugh, Jr., Esquire, Thomas W. Pippert, Esquire, Chad J. Peterman, Esquire and Alexis Deise, Esquire of Patterson, Belknap, Webb & Tyler LLP, New York, New York.

Frederick L. Cottrell, III, Esquire and Anne Shea Gaza, Esquire of Richards, Layton & Finger, P.A., Wilmington, Delaware. Counsel for Fournier Industrie Et Santé and Laboratoires Fournier, S.A. Of Counsel: William Baer, Esquire, James Cooper, Esquire and Anne P. Davis, Esquire of Arnold & Porter LLP, Washington, D.C.; Timothy C. Bickham, Esquire of Steptoe & Johnson LLP, Washington, D.C.

**** REVISED MEMORANDUM OPINION**

Dated: October 2, 2008
Wilmington, Delaware

ROBINSON, District Judge

I. INTRODUCTION

This is a consolidated antitrust action brought by various plaintiffs[1] (collectively "plaintiffs") against defendant Abbott Laboratories ("Abbott"), and Fournier Industrie et Sante′ and Laboratories Fournier S.A. (collectively, "defendants"). Before the court is defendants' motion for summary judgment on plaintiffs' claims of sham litigation and *Walker Process* violations. (Civ. No. 02-1512, D.I. 605; Civ. No. 03-120, D.I. 509; Civ. No. 05-340, D.I. 394; Civ. No. 05-360, D.I. 388)[2] For the reasons that follow, the court grants in part and denies in part the motion.

II. BACKGROUND

Plaintiffs assert that defendants, through an overarching scheme, impeded the market entry of the generic version of TRICOR®, a brand name drug used to control

---

[1]Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively, "Teva") brings antitrust claims as a counterclaim plaintiff. (Civ. No. 02-1512) Impax Laboratories, Inc. ("Impax") also brings antitrust claims as a counterclaim plaintiff. (Civ. No. 03-120)

On August 18, 2008, the court granted a motion for class certification brought by direct purchaser plaintiffs. Representatives of this class are Louisiana Wholesale Drug Co., Inc., Rochester Drug Co-Operative, Inc. and Meijer, Inc. and Meijer Distribution, Inc. (Civ. No. 05-340, D.I. 436)

The court also granted, in part, a motion for class certification brought by indirect purchaser plaintiffs (to the extent they bring federal claims). Representing the indirect purchaser plaintiffs are Cindy Cronin, Diana Kim, Sandra Krone, Alberto Litter, Neil and Helena Perlmutter, Elaine M. Pullman, Lula Ramsey, Charles M. Shain, Hector Valdes, Richard G. Wilde, Pennsylvania Employees Benefit Trust Fund, Allied Services Division Welfare Fund, Sheet Metal Workers International Association Local Union 28, Painters' District Council No. 30 Health and Welfare Fund, Philadelphia Employees Benefit Trust Fund, Philadelphia Federation of Teachers Health and Welfare Fund, and Vista Healthplan, Inc. (Civ. No. 05-360, D.I. 430) PacifiCare Health Systems, Inc. ("PacifiCare") brought a separate indirect purchaser action, which has been consolidated with the foregoing. (Civ. No. 05-591)

[2]Henceforth, docket item numbers ("D.I.") refer to documents filed in Civ. No. 02-1512, unless otherwise noted.

levels of cholesterol and triglycerides. Specifically, plaintiffs assert that defendants instituted a multi-faceted scheme, manipulating the statutory framework as set forth in the Hatch Waxman Act, to maintain a monopoly position in the market, consisting of: (1) "sham" litigations; (2) product conversions; and (3) other intentional wrongful behavior designed to further a monopoly.

More specifically, plaintiffs claim that defendants engaged in sham litigation by bringing two sets of ANDA lawsuits, both involving fenofibrate products marketed under the TRICOR® brand name: (1) in the district court for the Northern District of Illinois, alleging that fenofibrate capsules described in ANDAs filed by Novopharm (Teva)[3] and Impax infringe U.S. Patent No. 4,895,726 ("the '726 patent"); and (2) in this court, alleging that fenofibrate tablets described in ANDAs filed by Teva and Impax infringe U.S. Patent Nos. 6,074,670, 6,277,405, 6,589,552 and 6,652,881 (the "'670," "'405," "'552," and "'881" patents, respectively) (collectively, "the Stamm patents"). Plaintiffs also assert a *Walker Process* claim, accusing defendants of asserting the '881 patent while allegedly knowing that it is unenforceable due to inequitable conduct.

A. The '726 Patent and Mr. Reginault

Fenofibrate[4] is used to treat high levels of triglycerides and also has indications for lowering cholesterol. The '726 patent describes a novel dosage form of fenofibrate, gelatin capsules, containing fenofibrate and a solid surfactant which have been co-micronized. The capsules of the '726 patent were proclaimed to have a distinct

---

[3]Novopharm, Ltd. is a subsidiary of plaintiff Teva Pharmaceutical Industries, Ltd.

[4]Isopropyl 2-(4-(4-chlorobenzoyl)phenoxy)-2-methylpropionate.

advantage over prior art formulations. To wit,

> [i]t has now been discovered that the co-micronization of fenofibrate and a solid surfactant (i.e. the micronization of an intimate mixture of fenofibrate and a solid surfactant) makes it possible to improve the bioavailability of the fenofibrate to a significantly greater extent than that which would be achieved either by adding a surfactant, or by micronizing the fenofibrate on its own, or by intimately mixing the separately micronized fenofibrate and surfactant.

('726 patent, col. 1, ll. 35-43)

The application that led to the '726 patent was filed on January 19, 1989; the '726 patent issued on January 23, 1990, to Fournier, the application's assignee. Philippe Reginault, a Fournier scientist, is one of three named inventors of the '726 patent. Mr. Reginault served as Fournier's director of pharmaceutical development from 1988-2002. (D.I. 625 at TIJA-2046) Mr. Reginault was in charge of developing fenofibrate formulations; he testified that he was the only one with this responsibility. *(Id.)*

B. Mr. Reginault's Relationship with PharmaPass and the Stamm Patents

In 1996, Mr. Reginault evaluated technology from PharmaPass, a developer of controlled release technologies and formulations, in the context of acquiring a new fenofibrate formulation and related patent protection. (*Id.* at TIJA-2046, 2048) He met with personnel from PharmaPass on at least two occasions for this purpose. (*Id.* at TIJA-2046-47, 2227-28)

On September 26, 1996, Mr. Reginault sent to a Mr. A. Munoz of PharmaPass a memo in which he recommended that Fournier and PharmaPass enter into a contract "in order that . . . [w]e would introduce a new formulation onto the market (a matter for Marketing)[, and] [w]e would reshuffle the cards to cause problems for the generic

brands, even if the patent is weak and does not provide any protection against the development of a bioequivalent form by a different method." (*Id.* at TIJA-2228)

On October 17, 1996, Mr. Reginault sent a memo Mr. Munoz concerning "PharmaPass fenofibrate milestones." (*Id.* at TIJA-2171) Mr. Reginault stated that

> it would be important to include a milestone – which in my opinion is major – depending on the validity of the patent. Rather than having a solid patent, the most important point is to avoid being anticipated by the prior art.
>
> The milestone could be defined in calendar terms as follows: 18.5 months after the 1st patent has been filed, which would cover us for Europe and Canada.

(*Id.*) Mr. Reginault testified that this meant that no licensing payments would be made to PharmaPass for its formulation until a patent was granted in Europe and Canada. (*Id.* at TIJA-2063)

In December 1996, PharmaPass sent to Mr. Reginault's attention a graph of dissolution profile data, and informed him that results of their research was "negative." (*Id.* at TIJA-2167-68) The parties have not provided any additional information about this testing or set of results, and it is unclear to the court what the "negative" result actually was in context.[5]

The technology acquired by Fournier from PharmaPass can be summarized by French patent application FR 97 00479 ("the French priority application"), filed January 17, 1997. (*Id.* at TIJA-2231-54) The Stamm patents are all related to each other; each claim priority to the French priority application. The Stamm patents have essentially the

[5]It appears that a translated copy of this deposition exhibit was not provided to the court as part of the joint appendices. (D.I. 625)

same specification.[6]

The French priority application and the Stamm patents describe new fenofibrate formulations – tablet formulations – having improved dissolution and bioavailability. According to each of the Stamm patents,

> the preparation method in [the '726 patent][7] is not completely satisfactory inasmuch as it does not lead to complete bioavailability of the active ingredient, and suffers from several disadvantages. The technique of co-micronizing fenofibrate with a solid surfactant does, it is true, improve dissolution of the active ingredient, but this dissolution remains, however, incomplete.
>
> There is thus a need to improve fenofibrate bioavailability in order to attain, over very short periods of time, a level close to 100% (or, in any case, better than the following limits: 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes . . .) . . .
>
> Applicant has found that, surprisingly, it is possible to resolve this problem by a new method for preparing a pharmaceutical composition by spraying a suspension of the active ingredient onto an inert hydrosoluble carrier.

('881 patent, col. 2, ll. 14-37)

The Stamm patents disclose dissolution profiles for the new tablet formulation ("Stamm tablet") as compared to a prior art capsule formulation (the "'726 capsule"),[8] concluding that the new tablet formulation displays a "distinctly improved dissolution" compared to this prior art. The results reported in the Stamm patents (Example 2) were

---

[6]The Stamm patents have the same inventors, Andre Stamm and Pawan Seth, and are owned through assignment by Fournier and exclusively licensed in the United States to Abbott.

[7]The specifications cite to EP-A-0330532, the European publication number corresponding to the '726 patent.

[8]Testing was done on "lot 2177" of "Lipanthyl 200M," the trade name for the capsule formulation disclosed in the '726 patent. (D.I. 627 at TIJA-5166-67) For purposes of this opinion, the court describes as the "'726 capsule" all capsule formulations involving "lot 2177."

obtained using polysorbate 80 ("Tween"[9]) as the surfactant in the dissolution medium, insofar as it is "discriminating" ("two products having very different dissolution profiles in gastric juices will have very different dissolution curves"). ('670 patent, col. 7, ll. 57-60 (ex. 2)) Results are shown graphically in Figure 1. According to the inventors, "[t]hese results clearly show that the compositions according to the invention have a dissolution profile which is distinctly better than that of the prior art compositions." (*Id.*, col. 8, ll. 21-23)

Figure 2 contrasts dissolution profiles for these formulations and, in addition, several other prior art formulations "commercially available on the German market": "Normalip pro (200mg)," "Fenofibrat-Radiopharm (2 x 100mg)," and "Durafenat (2 x 100 mg"). Figure 2 is the same graph of dissolution profile data sent from PharmaPass to Mr. Reginault in December 1996. Again, "[t]hese results clearly show that the compositions of the invention have a distinctly improved dissolution compared to prior art compositions." (*Id.*, col. 9, ll. 41-43)

The French priority application disclosed (and claimed) one method for testing how well the new formulation of fenofibrate dissolved, that is, dissolving the formulation in water and Tween. (D.I. 625 at TIJA-2244-45) The Stamm patents disclose and claim using either 2% Tween or another dissolution medium, 0.025 molar sodium lauryl sulfate ("SLS"), to determine how well the formulation dissolved. (D.I. 626 at TIJA-3450)

SLS was being used as a dissolution medium by Fournier. After Mr. Reginault

---

[9]Generally, a nonionic surfactant and emulsifier derived from polyethoxylated sorbitan and oleic acid.

began working with PharmaPass in 1996, the decision was made, jointly by Mr. Reginault and a member of PharmaPass's pharmaceutical development team, to begin using SLS. (D.I. 625 at TIJA-2054-55) Mr. Reginault tried to obtain the same rapid dissolution profile with SLS that Mr. Stamm had achieved with Tween.[10] (*Id.* at TIJA-2055) Pascale Blouquin, a member of Mr. Reginault's team, undertook a study to determine what amount of SLS should be added to water to obtain results similar to the Tween testing, in other words, what percentage of SLS would discriminate between tablet and capsule formulations. (*Id.* at TIJA-2055-56) Ms. Blouquin reported her results in a May 1997 memo, addressed to Mr. Reginault ("the Blouquin memo").[11] (*Id.* at TIJA-2076-78)

In September 1997, Fournier presented information regarding bringing fenofibrate to market in the United States to Abbott for the purposes of Abbott's due diligence. Mr. Reginault participated in Fournier's presentation regarding potential patent exclusivity. (D.I. 626 at TIJA-3375)

Ms. Blouquin, as part of her dissolution testing with SLS, tested a particular batch of '726 capsules. (*Id.* at TIJA-2079) Dissolution data for the '726 capsules, obtained with Tween, was contained in the first in the chain of the Stamm patent

---

[10]Mr. Reginault was "responsible for technical issues" arising within the licensing relationship with PharmaPass. (D.I. 625 at TIJA-2048) Mr. Reginault testified that the relationship with Mr. Stamm at PharmaPass was his "reserved area." (*Id.*) Notwithstanding, his team members were not precluded from having contact with Mr. Stamm. (*Id.*)

[11]A second, undated memo containing additional data is also of record. (D.I. 625 at TIJA-2153-66) The parties have not focused their arguments on this second memo or the data contained therein.

applications, U.S. Patent Application No. 09/005,128 ("the '128 application"), filed on January 9, 1998, and later issuing as the '670 patent. The two sets of data are provided and contrasted below.

Time	**Blouquin memo testing May 1997**	**Fig. 1 of the '670 patent filed as '128 application in January 1998**
	surfactant: 0.025 M SLS	**surfactant: Tween**
5 min	1.60%	0%
10 min	19.68%	3.7%
20 min	55.40%	31.2%
30 min	67.70%	54.9%

According to Teva's expert, and as indicated above, the '726 capsule dissolved better in SLS than Fournier reported in the '128 application and the remainder of the Stamm patents.[12] (D.I. 624 at TIJA-0156-58) The Blouquin data was not disclosed to the PTO.

The following represents a comparison of the foregoing with the dissolution rate claimed for the tablet formulation of the invention of the '670 patent, the "Stamm tablet."

[12]The '405, '552, and '881 patents issued as a series of continuations from the '128 application.

Time	'726 capsule (source: Fig. 1 of the '670 patent)	'726 capsule (source: Blouquin memo)	Stamm tablet (source: Fig. 1 of the '670 patent)
	Tween	0.025 M SLS	Tween
5 min	0%	1.60%	18.9%
10 min	3.7%	19.68%	67.1%
20 min	31.2%	55.40%	89.7%
30 min	54.9%	67.70%	95.9%

During the prosecution of the '128 application, the applicants twice asserted that the formulation of the Stamm tablet had a better dissolution profile than that of the '726 capsule.[13] The Notice of Allowability for the '670 patent, dated January 14, 2000, provided:

> As stated in applicants' remarks filed on 11/17/99, the present fenofibrate composition exhibits an improved dissolution and bioavailability profile[ ] as compared to the prior art. The present composition utilizes an increased amount of hydrophilic polymer (at least 20% by weight), and the prior art neither teaches nor suggests that the dissolution or bioavailability profiles can be improved with the claimed amount of hydrophilic polymer, in addition to the remaining components.

(*Id.* at TIJA-3476) The '670 patent issued June 13, 2000, claiming an immediate

[13]An Office Action was mailed on August 10, 1998 rejecting pending claims 1-34 of the '128 application as obvious in view of the '726 patent and other references. In traversing the rejection, which asserted "that the dissolutions of the present compositions and the compositions described in [the '726 patent] are comparable," the applicants "respectfully submit[ted] that a fair comparison between [the '726 patent] and the present invention has been made in Example 2 of the specification." (D.I. 626 at TIJA-3470) The Notice of Allowability also makes mention of applicants' remarks dated November 17, 1999 concerning improved dissolution. (*Id.* at TIJA-3476)

release fenofibrate composition.[14]

In April 2000, Mr. Reginault authored a "Developmental Report" based on memos and reports he had received from his team members. (D.I. 625 at TIJA-2058) The Developmental Report contained a table from the Blouquin memo. (*Id.* at TIJA-2131, 2160) This data was dissolution profile data of fenofibrate 54 mg tablets and 67 mg Tricor® capsules.[15] (*Id.*) The data for the 67 mg Tricor® capsules is reproduced below. For purposes of comparison, the dissolution profiles from Figure 1 of the '670 patent, Blouquin memo, and claim 2 of the '670 patent are provided for comparison.

Time	**'726 capsule (source: Fig. 1 of the '670 patent)** **'128 application filed in January 1998**	**'726 capsule (source: Blouquin memo)** **May 1997**	**Tricor® 67 mg capsule (source: Developmental Report)** **2000**	**Stamm tablet (Claim 2 of the '670 patent)** **'128 application filed in January 1998**
	Tween	**0.025 M SLS**	**0.025 M SLS**	**2% Tween, or 0.025 M SLS**
5 min	0%	1.60%	8.1%	>10%
10 min	3.7%	19.68%	32.9%	>20%
20 min	31.2%	55.40%	64.4%	>50%
30 min	54.9%	67.70%	75.6%	>75%

[14]The '405 patent was filed thereafter in May 2000 as a continuation of the '128 application, and claimed a composition comprising a hydrosoluble carrier and micronized fenofibrate having a specific dissolution profile. The '405 patent issued on August 21, 2001. The '552 patent was filed as a continuation application in April 2002, and claims a granulated fenofibrate composition. The '552 patent issued on July 8, 2003.

[15]It is unclear to the court whether the Tricor® 67 mg capsule is also covered by the '726 patent.

As the foregoing indicates, two data sets obtained for '726 capsules fall within the patented dissolution profile of the Stamm tablet at several points.

Mr. Reginault testified regarding his relationship with the people in the patent division of Fournier's legal department regarding fenofibrate patents. (D.I. 625 at TIJA-2049) More specifically, he "explained the [fenofibrate] product to them, explained what the formulation was and did so in simple terms for someone who was not familiar with it." (*Id.*) In 2001, Mr. Reginault participated in an "audit" of the fenofibrate patents with counsel. (D.I. 626 at TIJA-3322)

The continuation application that led to the '881 patent was filed in November 2002 ("the '425 application"). The '425 application included a specific disclosure of using "co-micronized" fenofibrate in the new formulation, which was not disclosed in the French priority application. The '881 patent claims a composition containing micronized fenofibrate having a specific dissolution profile, a tablet form of micronized fenofibrate, a layered formulation having an inert carrier and outer fenofibrate layers, a granulated capsule form, and a granulate.

On February 19, 2003, the examiner rejected claims 1-14 and 22-41 of the '425 application as obvious in view of the '726 patent. (D.I. 627 at TIJA-5146) Fournier distinguished the dissolution profile of the '726 patent.[16]

On June 16, 2003, Mr. Reginault executed a technical declaration to the PTO in connection with the '425 application. (D.I. 625 at TIJA-2066-71) The declaration

---

[16]The court does not have before it complete file wrappers for the Stamm patents. The exact contents of Fournier's response have not been detailed by the parties. In addition, the precise nature of the rejection preceeding Mr. Reginault's declaration cannot be recounted.

contained dissolution data, and stated that "[i]t is my opinion that the claimed invention has a superior dissolution profile when compared to the dissolution profile of U.S. Patent No. 4,800,079 to Boyer."[17] (*Id.* at TIJA-2070) Mr. Reginault testified that he prepared the declaration jointly with patent attorneys. (*Id.* at TIJA-2051) He further testified that he "was sure that [he] understood what [he] wrote"; he "did not write the legal parts, [he] wrote the science parts and understood, obviously, what [he] was writing[.]" (*Id.*)

When the examiner allowed the claims, he stated that

> [t]he prior art fails to teach the instantly claimed composition having a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes. . . . The instant invention, as seen in Example 2, has an unexpectedly superior dissolution profile compared to Lipanthyl® 200M (as taught by Curtet). Curtet does not disclose, nor provide motivation to achieve the instant dissolution profile.[18]

Mr. Reginault acknowledged that "the differences between [the] two dissolutions, the PharmaPass formulation and the [co-micronized formulation] . . . formed the basis of the ['881] patent." (D.I. 625 at TIJA-2053) The '881 patent issued on November 25, 2003.

On September 23, 2005, Mr. Reginault executed a declaration in connection with

---

[17]The declaration provided dissolution data for two products: Lipanthyl® 250 (manufactured by Ethypharm and marketed by Fournier), and Lipanthyl® Supra (manufactured and marketed by Fournier). It appears from the declaration that Lipanthyl® Supra was a product made by a process described and claimed in the '425 application. (D.I. 625 at TIJA-2068) In contrast, Lipanthyl® 200 was made by a process taught in U.S. Patent No. 4,800,079 to Boyer. (*Id.*) This patent generally describes a fenofibrate capsule formulation.

[18]The court includes plaintiffs' recitation of the prosecution history; defendants provide no corrections and do not dispute this text in its reply papers.

the present litigation. (Civ. No. 05-360, D.I. 392 at DJA-47-52) In his declaration, Mr. Reginault states that he "was not involved in preparing the original French patent application filed in January 1997, nor was [he] consulted on the substance of the application." (*Id.* at ¶ 11) Aside from his 2003 declaration, Mr. Reginault states that he was not consulted or involved in the subsequent prosecution of the Stamm patents. (*Id.* at ¶ 19) Further, the declaration states:

> I certainly do not believe that in June 2003 I had a memory of the 1997 [Blouquin] memo or of the specific dissolution data in it to which Teva cites because, among other things, once the Formulation Department had confirmed that 0.025 M SLS was an appropriate substitute for Tween 80, there would have been no reason to give the data any further thought. My only recollection was that it was concluded that 0.025 M SLS was an appropriate substitute.

(*Id.* at ¶ 22) Accordingly, Mr. Reginault states that he authored the 2003 declaration without recall of the Blouquin data. (*Id.* at ¶ 24)

C. Defendants' Market Conduct (The So-Called "Sue and Switch")

The court has previously detailed in its prior opinion plaintiffs' allegations regarding defendants' market switches;[19] the following is provided for summary purposes.

Defendants received FDA approval for fenofibrate capsule products in 2000, and

---

[19] *See Teva Pharmaceuticals USA, Inc. v. Abbott Labs.*, Nos. Civ. A. 02-1215, 03-120, 05-340, 05-360, 2008 WL 3849696 (D. Del. Aug. 18, 2008). The court took the allegations in the direct purchaser's complaint as true for purposes of the court's prior background section, and cited primarily to that complaint. (Civ. No. 05-340, D.I. 29) In its prior opinion, the court outlined defendants' conduct with respect to its launch of, and subsequent withdrawl of, different TRICOR® formulations from market. No inferences are to be granted in favor of plaintiffs on summary judgment; to the extent the court's prior factual record affords plaintiffs such inferences, they do not play a role in the court's consideration of the issues at bar. The court also notes that the parties do not dispute the facts as previously presented in their summary judgment papers. Instead, additional facts are presented for purposes of the motion at bar, as discussed below.

sold fenofibrate capsules (collectively, "TRICOR®-A"[20]) throughout 2000 and 2001. The '726 patent was listed in the Orange Book as covering TRICOR®-A. Abbreviated New Drug Applications ("ANDA"s) were filed by Teva and subsequently by Impax, each containing paragraph IV certifications for the '726 patent. Defendants initiated three lawsuits in the district court for the Northern District of Illinois, and the cases were consolidated (collectively, the "capsule litigation"). Defendants' suits triggered successive 30-month stays on ANDA approval by the FDA.[21] In March 2002, the Illinois district court granted Teva's motion for summary judgment of non-infringement; the Federal Circuit subsequently affirmed. While the appeal before the Federal Circuit was pending, Teva received FDA approval to market its generic fenofibrate capsule formulations; Teva entered the market shortly thereafter.

While the capsule litigation was pending, defendants began developing tablet formulations of TRICOR® (collectively, "TRICOR®-B"[22]). The FDA granted defendants approval to market TRICOR®-B tablets in September 2001; at this time, however, the 30-month stay triggered by the capsule litigation remained in effect. Defendants then stopped all new sales of TRICOR®-A and directed their sales force to sell only TRICOR®-B. Defendants listed the '726, '670 and '405 patents in the Orange Book as covering TRICOR®-B. In or about December 2001, defendants listed TRICOR®-A as an obsolete drug in the National Drug Data File; this caused the corresponding

---

[20]Three capsule formulations were sold under the TRICOR®-A brand name: 67 mg, 134 mg and 200 mg capsules.

[21]See 21 U.S.C. § 355(j)(5)(B)(iii).

[22]TRICOR®-B includes 54 mg and 160 mg tablet strengths.

TRICOR®-A generic to be identified as a brand drug. According to plaintiffs, this resulted in a higher insurance co-payment for these drugs.

Teva, and subsequently Impax, filed ANDAs for generic TRICOR®-B in 2002, containing paragraph IV certifications. Defendants brought suit on each of the listed patents in the district court for the District of Delaware. The first complaint alleged infringement of the '726, '670, and '405 patents. A second complaint asserted infringement of the '552 patent, and a third complaint was filed alleging infringement of the '881 patent – these patents issued in 2003, and were subsequently listed in the Orange Book for TRICOR®-B.

Defendants' suits triggered successive 30-month stays on ANDA approval.[23] The Delaware cases were consolidated (collectively, the "tablet litigation"). Tentative approval to Impax's and Teva's ANDAs was granted by the FDA; final approval would have been granted on March 5, 2004 absent the stay. Defendants dismissed the tablet litigation with less than a month before trial, which had been postponed from December 2004 to June 6, 2005, to allow defendants the opportunity to bring suit on the later-issuing patents.

While the tablet litigation was pending, defendants implemented a second market switch, this time from TRICOR®-B tablets to TRICOR®-C tablets, which differed from TRICOR®-B only in the dosage strength. The second conversion was executed with a series of steps similar to those defendants had employed in the first conversion.

---

[23]As discussed in the court's prior opinion, the complaints filed by defendants, with the exception of that relating to the '881 patent, triggered successive stays, insofar as they preceded amendments made to the Hatch Waxman Act, which limited the amount of stays obtained per ANDA.

The FDA approved defendants' NDA for TRICOR®-C in November 2004. The new dosage strengths of TRICOR®-C precluded generic substitution of those ANDAs approved from TRICOR®-B.

D. Litigation History

1. The capsule litigation

The '726 patent claims a therapeutic composition "containing a co-micronized mixture of particles of fenofibrate and a solid surfactant[.]" Teva asserted that this limitation should be construed to mean that fenofibrate and a solid surfactant have been micronized together and in the absence of other excipients; defendants asserted that other excipients are not precluded. The Illinois court disagreed with defendants, since during prosecution, "[Fournier] distinguished its claims, in part, on the fact that fenofibrate and a solid surfactant would be micronized together. In every instance, no other materials are included in this co-micronization." Further, "[b]y distinguishing its co-micronized mixture from these types of mixtures, [the patented] co-micronized mixture cannot include such mixtures." *Abbott Labs. v. Novopharm Ltd.*, Nos. Civ. A. 00-2141, 00-5094, 01-1914, 2002 WL 433584, *7 (N.D. Ill. Mar. 20, 2002) ("*Abbott I*").

Teva's capsules are manufactured by micronizing fenofibrate by itself, then dry-mixing the micronized fenofibrate with several other ingredients. This dry fenofibrate mixture is added to a granulating solution (made by dissolving SLS and povidone in water). The resulting mixture is subjected to a wet granulation process involving mixing and the addition of more water, after which the mixture is dried, dry blended with additives, and eventually encapsulated. *Id.* at *3-4.

In view of the foregoing, the Illinois court granted summary judgment of non-infringement in favor of Teva, insofar as there was no dispute that Teva did not co-micronize fenofibrate and a solid surfactant in the absence of other excipients in its process. *Id.* at *8. The court also noted that Fournier "specifically distinguished its co-micronized product and co-micronization process from those obtained from micronizing fenofibrate itself," specifically distinguishing prior art on the basis of the resultant improvement in bioavailability. For this reason, Teva, which pre-micronizes fenofibrate by itself, could not infringe under the doctrine of equivalents as a matter of law. *Id.* at *8-9.

On appeal, the Federal Circuit affirmed, stating the following:

> Had that term not been explicitly defined in the '726 patent specification, we might well agree with the appellants that that term could simply mean "micronized with or together" and would not necessarily exclude the presence of ingredients not specifically recited in the claim. However, the phrase "co-micronization of fenofibrate and a solid surfactant" is in fact explicitly defined at column 1, lines 35-38, of the '726 patent, as "micronization of an intimate mixture of fenofibrate and a solid surfactant." Hence, this is a case in which the patentee has "chosen to be his own lexicographer," and the district court did not err by reading the patentee's definition from the specification into the claim. Moreover, the inclusion of the word "intimate" in the definition, together with the fact that fenofibrate and SLS are the only ingredients present in every co-micronized mixture described in the '726 patent's specification, makes it **abundantly clear** that "co-micronization of . . .fenofibrate and a solid surfactant" should be construed as referring to co-micronization of a mixture consisting essentially of fenofibrate and solid surfactant [not excluding the possibility of minor impurities being present].

Abbott Labs. v. Novopharm Ltd., 323 F.3d 1324, 1330 (Fed. Cir. 2003) ("*Abbott II*") (emphasis added). The Federal Circuit also stated that, even notwithstanding, Teva's product could not infringe because SLS, which "dissolve[s] in the aqueous granulating solution prior to mixing with the fenofibrate and remains in solution throughout the wet

granulation and drying steps," is "clearly" not a "solid surfactant" as required by the claims. *Abbott II* at 1331.

Shortly after the Federal Circuit issued its decision, Impax moved for summary judgment in the copending litigation. The Illinois court found that it was bound to apply the prior claim construction by reason of collateral estoppel, but noted that, even if it were not so bound, it would nonetheless construe "co-micronized" as fenofibrate and a solid surfactant micronized together in the absence of other excipients for the same reasons noted in the *Abbott I* decision.[24] *Abbott III,* 2003 WL 1563426 at *5.

Impax manufactures fenofibrate capsules by a process where pre-micronized fenofibrate (i.e., fenofibrate micronized by itself) is added to other excipients, and then a liquid surfactant is added to the dry mixture to cause wet granulation. *Id.* at *6.

---

[24]Specifically:

> The court notes that even if it were not bound to follow Judge Darrah's ruling, it would nonetheless similarly construe the claims. First, the court would look to the ordinary meaning of "co-micronized" to find that it means "to reduce to a fine powder [micronize] with or together." Dorland's Illustrated Medical Dictionary 368, 389 (29th ed. 2000). Next, as Judge Darrah did, the court looks to the claim language, specification, and prosecution history and concludes that a "co-micronized" mixture includes fenofibrate and a solid surfactant that have been micronized together in the absence of any other excipients. Nowhere in the claims, specification, or prosecution history are any other materials identified as being part of this mixture. Further, in the specification and prosecution history, the patentee distinguished its co-micronized mixture from mixtures obtained by adding a surfactant to fenofibrate, or micronizing fenofibrate by itself, and/or mixing separately micronized fenofibrate and a surfactant. Like Judge Darrah, this court concludes that "co-micronized" and "co-micronization" means that fenofibrate and a solid surfactant have been micronized together in the absence of other excipients.

Abbott Labs. v. Impax Labs., Inc., Nos. Civ. A. 00-5092, 00-7865, 01-1648, 2003 WL 1563426, *5 (N.D. Ill. Mar. 26, 2003) ("*Abbott III*").

Because Impax does not have "a manufacturing step where there is a mixture of particles consisting solely of fenofibrate and a solid surfactant," Impax could not infringe as a matter of law. *Id.* at *7. Additionally, for the same reasons expressed in *Abbott I*, defendants could not assert the doctrine of equivalents.[25] *Id.* The *Abbott III* court granted summary judgment of non-infringement. *Id.* The action was thereafter terminated by agreement of the parties.

2. The tablet litigation

In the tablet litigation, the parties disputed the construction of eight claim terms. For the majority of those terms, the Delaware court adopted the constructions advocated by Abbott and Fournier. (D.I. 318) Teva and Impax filed nine summary judgment motions on the issues of infringement, best mode, enablement, and indefiniteness. The court denied six of those motions and denied two others in part.

---

[25]The court explained:

> [E]ven if the court were not bound under collateral estoppel, the court is persuaded by Judge Darrah's reasoning and would similarly bar Fournier from relying on a doctrine of equivalents argument. In [*Abbott I*], the court looked to the prosecution history and found that the patentee of the '726 patent distinguished its process and product from those achieved by adding a surfactant or by micronizing the fenofibrate on its own or by intimately mixing the separately micronized fenofibrate and surfactant. Therefore, "based on the arguments made during the prosecution of the patent ... and the arguments made during reexamination," the court concluded that "[Fournier] relinquished a product and process that involved either adding a surfactant by itself or by micronizing the fenofibrate on its own [as done by Teva] or by intimately mixing the separately micronized fenofibrate and surfactant." [*Abbott I*, 2002 WL 433584] at *24-25. Like the defendant in [*Abbott I*], Impax's process uses fenofibrate that has been micronized by itself. As did [the *Abbott I*] court, the court concludes that Fournier is estopped from arguing infringement under the doctrine of equivalents for claims 1 or 10.

Abbott III, 2003 WL 1563426 at *7.

(D.I. 333; Civ. No. 03-120, D.I. 257) The court granted partial summary judgment in favor of Teva and Impax on the issue of infringement of the '552 patent and on claim 9 of the '405 patent.[26] More specifically, the court found that Teva's and Impax's generic products did not have a "hydrophilic polymer" under the court's claim construction, as required by those claims.

For this term, Teva and Impax proposed a claim construction reflecting the disclosure in the specification that "[t]he expression 'hydrophilic polymer' in the invention should be taken to mean any high molecular weight substance (greater, for example, than 300) having sufficient affinity towards water to dissolve therein and form a gel." *Abbott Labs. v. Teva Pharms. USA, Inc.*, Nos. Civ. A. 02-1512, 03-120, 2005 WL 1026746, *7 (Apr. 22, 2005) (citing '670 patent, col. 4, ll. 14-17). Abbott asserted that this construction was inconsistent with one statement in the specification, reading "[d]epending on polymer solubility, [the hydrophilic polymer] either dissolves in the solution or forms a gel or a suspension having varying degrees of thickness." *Id.* (citing '670 patent, col. 6, ll. 25-27). The court disagreed:

> As noted by Abbott, this portion of the specification states that the hydrophilic polymer "either dissolves in the solution or forms a gel or a suspension," but does not both dissolve and form a gel, as the portion of the specification defining the term requires. Counsel for Abbott, however, was unable to articulate for the court why the statement "[t]he solvent employed can be aqueous or organic" does not relieve any perceived inconsistency in the use of the term hydrophilic polymer.
>
> * * *
>
> [I]f the suspension contained an aqueous solvent, the polymer would be affected

[26]Summary judgment was granted on the '670 patent (on a speaking motion) because defendants had no expert opinion on the issue of infringement of that patent.

> differently than if the suspension contained an organic solvent. Such a difference would explain why this portion of the specification states that the hydrophilic polymer "either dissolves in the solution or forms a gel or a suspension," rather than stating that the hydrophilic polymer dissolves and forms a gel, as its definition requires it to do in water. Thus, the specification does not use the term "hydrophilic polymer" in a manner inconsistent with the explicit definition provided by the patentees acting as their own lexicographers[.]

Id. at *8. In view of this "clear[ ] and explicit[ ]" definition in the specification, and Abbott's inability to justify its position, the court rejected Abbott's construction. *Id.* at *7-8. Based upon this construction, summary judgment of noninfringement was granted to Impax, insofar as its two excipients[27] were not "hydrophilic polymers" under the court's definition. (Civ. No. 03-120, D.I. 257 at 25)

The case was ripe to proceed to trial on defendants' claims of infringement of the '405 and '881 patents. In this regard, defendants asserted that Impax's excipient, crosscarmellose sodium ("Ac-Di-Sol®"), met the "hydrosoluble carrier" limitation of the claims under the doctrine of equivalents. Ac-Di-Sol® is not hydrosoluble, it is hydroswellable – meaning it takes up water and swells, which ruptures the tablet into chunks. Defendants' expert, Dr. Stephen R. Byrn, agreed that Ac-Di-Sol® is not water soluble,[28] but nevertheless asserted that Ac-Di-Sol® functions in an equivalent "way" because it facilitates the exposure of fenofibrate to water. (Civ. No. 05-360, D.I. 392 at DJA-492-93) An internal Fournier document, authored by Maurice Tendero and dated September 28, 1998, reflects the opinion that "[r]eplacing the water-soluble excipient by

---

[27]Hydroxypropylmethylcellulose ("HPMC") and microcrystalline cellulose ("MCC").

[28]Indeed, Dr. Byrn could not reasonably assert the contrary. The Handbook of Pharmaceutical Excipients lists Ac-Di-Sol® as "insoluble in water." (D.I. 627 at TIJA-5156)

a non-water-soluble excipient is actually beyond the scope of the PharmaPass patent." (D.I. 625 at TIJA-2271.1) Impax did not move for summary judgment on this issue. Defendants dropped their claims a month prior to trial, and executed a covenant not to sue,[29] depriving the court of jurisdiction to try Impax's declaratory judgment claims as to the '405 and '881 patent.

3. The present antitrust litigation

Teva and Impax's antitrust counterclaims remain pending before the court. (Civ. No. 02-1512, D.I. 360, ex. A (Teva); Civ. No. 03-120, D.I. 355, ex. A (Impax)) Early in the litigation, defendants filed a consolidated motion to dismiss plaintiffs' "sham litigation" and *Walker Process* claims, which claims allege that defendants proceeded without a reasonable basis for asserting that the accused products infringed their patents, that is, that defendants did not conduct a "good faith, informed comparison of the claims of [their] patent[s] against the accused subject matter."[30]** *See Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408, 426 (D. Del. 2006) (citing *Q-Pharma Inc. v. Andrew Jergens Co.*, 360 F.3d 1295, 1302 (Fed. Cir. 2004) (brackets in

---

[29]Judge Jordan remarked:

> [H]ere is what I see [Abbott and Fournier have] done. They have walked me to within less than three weeks of a trial date and taken [Impax and Teva] through a substantial and very expensive round of international discovery and now, at this moment when they're entitled to get some answers on invalidity and unenforceability the way you felt entitled to get an answer on infringement, you're trying to say, well, it all goes away because we changed our mind. So I have to say it leaves me a little cold.

(D.I. 627 at TIJA-5064)

[30]All plaintiffs **[* * *]** assert that defendants pursued the tablet litigation without probable cause.

original)). Defendants asserted that the fact that they lost the capsule litigation on summary judgment, due to a losing claim construction argument, did not demonstrate a lack of probable cause. *Id.* The court noted that defendants "point[ed] to nothing in the published opinions that establishe[d] as a matter of law that defendants had probable cause to bring suit." *Id.* Further,

> [a]s to the allegations based on the tablet litigation, defendants argue that I may take judicial notice of the summary judgment opinion I issued, which, according to defendants, demonstrates that there was probable cause to bring those suits. (D.I. 384 at 19-20) However, defendants point to nothing in that opinion that establishes as a matter of law that defendants had probable cause to bring suit. Given plaintiffs' allegations concerning the lack of a good faith infringement analysis and the knowing assertion of unenforceable patents, factual issues which are not addressed in the opinion relied on by defendants, I will not dismiss the present claims at the pleading stage.

Id.

By order dated August 18, 2008, the court stayed the state law claims of the indirect purchaser plaintiffs (state law antitrust, consumer protection, unjust enrichment) and counterclaim plaintiffs (state law tortious interference). Continuing to trial in this consolidated action are the following Sherman Act claims. Teva claims that defendants violated section 2 in the following ways: defendants have conspired to monopolize the fenofibrate market, engaged in an overall scheme to monopolize this market, attempted to monopolize this market, engaged in sham litigation, committed fraud during the prosecution of the '881 patent, and have improperly listed patents in the FDA's Orange Book. Teva also claims that defendants violated section 1 by entering into a contract, combination, or conspiracy in restraint of trade, and by using sham litigation to restrain trade. (D.I. 360, ex. A at ¶¶ 276-368)

Impax claims that defendants violated the Sherman Act by entering into a

conspiracy to restrain trade, in violation of Section 1, and by attempting to monopolize, conspiring to monopolize, and unlawfully monopolizing the fenofibrate market in violation of Section 2. (Civ. No. 03-120, D.I. 355, ex. A, ¶¶ 165-195) The direct purchaser plaintiffs make the same Section 1 claim and also advance an unlawful monopolization claim under Section 2, for which they seek injunctive relief. (Civ. No. 05-340, D.I. 29 at ¶¶ 160-184, D.I. 30 at ¶¶ 115-127; D.I. 31 at ¶¶ 123-36) The indirect purchaser plaintiffs and PacifiCare seek injunctive relief under the Clayton Act for defendants' alleged violations of Section 2. (Civ. No. 05-360, D.I. 24 at ¶¶ 107-125, D.I. 35 at ¶¶ 180-209)

III. STANDARD OF REVIEW

A court shall grant summary judgment only if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56©. The moving party bears the burden of proving that no genuine issue of material fact exists. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.10 (1986). "Facts that could alter the outcome are 'material,' and disputes are 'genuine' if evidence exists from which a rational person could conclude that the position of the person with the burden of proof on the disputed issue is correct." *Horowitz v. Fed. Kemper Life Assurance Co.*, 57 F.3d 300, 302 n.1 (3d Cir. 1995) (internal citations omitted). If the moving party has demonstrated an absence of material fact, the nonmoving party then "must come forward with 'specific facts showing that there is a genuine issue for trial.'" *Matsushita*,

475 U.S. at 587 (quoting Fed. R. Civ. P. 56(e)). The court will "view the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion." *Pa. Coal Ass'n v. Babbitt*, 63 F.3d 231, 236 (3d Cir. 1995). The mere existence of some evidence in support of the nonmoving party, however, will not be sufficient for denial of a motion for summary judgment; there must be enough evidence to enable a jury reasonably to find for the nonmoving party on that issue. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). If the nonmoving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

IV. DISCUSSION

Plaintiffs assert that both the capsule and tablet litigations were shams because defendants had no objectively reasonable basis to bring either suit, as: (1) defendants had no reasonable basis for alleging infringement in either case;[31] and (2) defendants alleged infringement in the tablet litigation while having no reasonable basis to believe

---

[31]By letter dated September 2, 2008, plaintiffs informed defendants and the court that "they do not intend to pursue, in their case in chief, the allegations that defendants engaged in sham litigation by unreasonably asserting that Teva and Impax infringed defendants' patents." (Civ. No. 03-120, D.I. 553) That is, although plaintiffs seek to reserve their right to present evidence regarding non-infringement at trial "if necessary to rebut affirmative evidence of infringement presented by defendants," plaintiffs "will under no circumstances, even on rebuttal, seek to present evidence that defendants' infringement theories were shams." (*Id.*, D.I. 556)

The parties have put the court in an awkward position, procedurally. Plaintiffs have not withdrawn any claims, and defendants have not withdrawn their summary judgment motion with respect to this portion of plaintiffs' claims. No joint stipulations of any kind have been filed. Therefore, while it appears that some kind of agreement could have been (and should have been) reached between the parties ending this matter, the court has no choice but to address defendants' motion in its entirety.

the Stamm patents were enforceable, i.e., defendants committed inequitable conduct and/or committed *Walker Process* fraud with respect to one or more of the Stamm patents.[32] Defendants have moved for summary judgment of "no sham litigation" and no *Walker-Process* violations. (Civ. No. 02-1512, D.I. 605; Civ. No. 03-120, D.I. 509; Civ. No. 05-340, D.I. 394; Civ. No. 05-360, D.I. 388)

A. Noerr-Pennington Immunity

A party who petitions the government for redress generally is immune from antitrust liability. *Eastern R.R. Presidents Conference v. Noerr Motor Freight*, 365 U.S. 127 (1961); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965). Commonly referred to as the *Noerr-Pennington* doctrine, this immunity extends to persons who petition all types of government entities, including legislatures, administrative agencies, and courts. *California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972). Although originally developed in the antitrust context, courts have applied this doctrine universally to business torts. *See Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119, 128-29 (3d Cir. 1999) (applying the doctrine to common law claims of malicious prosecution, tortious interference with contract, tortious interference with prospective economic advantage, and unfair competition); *see also IGEN Int'l, Inc. v. Roche Diagnostics GmbH*, 335 F.3d 303, 310 (4th Cir. 2003).

1. "Sham" litigation

Noerr-Pennington immunity is subject to two exceptions. A patent owner may be subject to antitrust liability for the anticompetitive effects of bringing suit if the accused

[32]Defendants are incorrect in their assertion that plaintiffs also assert a sham litigation claim based upon invalidity. (D.I. 622 at 20; Civ. No. 03-120, D.I. 555)

infringer proves that the suit was "a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." *Eastern R.R. Presidents Conference*, 365 U.S. at 144. In this regard, the Supreme Court has outlined a two-part test to determine whether the "sham litigation" exception applies. *See Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Ind.*, 508 U.S. 49 (1993). As an objective first part, "the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." Id. at 60. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, then the suit does not qualify as sham litigation and is immunized under the *Noerr-Pennington* doctrine. *Id.* The subjective second part of the definition arises only if the challenged litigation is objectively meritless. In such a case, the court must decide whether the "baseless lawsuit conceals 'an attempt to interfere directly with the business relationships of a competitor.'" *Id.* at 60-61. To invoke the "sham" exception, a defendant must prove, by clear and convincing evidence, that a plaintiff's activities were not really efforts to vindicate its rights in court. *See C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1368-69 (Fed. Cir. 1998) ("sham litigation requires more than a failed legal theory") (quoting *Handgards, Inc. v. Ethicon, Inc.*, 743 F.2d 1282, 1288 (9th Cir. 1984)); *MCI Communications v. Am. Telephone and Telegraph Co.*, 708 F.2d 1081, 1155 (7th Cir. 1983).

2. *Walker Process* fraud

A second exception to *Noerr-Pennington* immunity applies where an accused infringer shows that the asserted patent was procured through "knowing and willful

fraud" within the meaning of *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965) ("*Walker Process* fraud"). The plaintiff in the patent infringement suit must also have been aware of the fraud when bringing suit. *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1069 (Fed. Cir. 1998) (citing *Walker Process*, 382 U.S. at 177 & n.6).

Walker Process fraud is distinguished from the lesser offense of inequitable conduct, which is a "broader, more inclusive concept than the common law fraud needed to support a *Walker Process* counterclaim." *Id.* (citations omitted). Regarding inequitable conduct, courts look at "the equities of the particular case and determine whether the conduct before them . . . was so reprehensible as to justify the court's refusing to enforce the rights of the party guilty of such conduct." *Id.* (quoting *Norton v. Curtiss*, 433 F.2d 779, 793 (Fed. Cir. 1970)). In contrast, *Walker Process* fraud is generally held not to exist absent: "(1) a representation of a material fact, (2) the falsity of that representation, (3) the intent to deceive or, at least, a state of mind so reckless as to the consequences that it is held to be the equivalent of intent (scienter), (4) a justifiable reliance upon the misrepresentation by the party deceived which induces him to act thereon, and (5) injury to the party deceived as a result of his reliance on the misrepresentation." *Id.* (quoting *Norton*, 433 F.2d at 792-93 (citations omitted)).

B. Analysis

To proceed with its litigation-based antitrust claims,[33] plaintiffs must establish, by clear and convincing evidence, that defendants' lawsuits were objectively baseless or,

---

[33]I.e., those relating to petitioning activity.

alternatively, that the Stamm patents were procured through knowing or willful fraud on the PTO. The question at bar, therefore, is whether plaintiffs can establish the foregoing on the record before the court.[34]

1. Probable cause for asserting infringement

a. Capsule litigation

Plaintiffs assert that defendants could not have reasonably expected success on the merits at the time the capsule litigation was filed. Defendants concede that the capsule litigation turned on the court's construction of "co-micronize." (Civ. No. 05-360, D.I. 389 at 2) The '726 patent specifically defines what "co-micronization" means: "It

---

[34]The parties dispute the manner in which the summary judgment standard applies to the present case. Plaintiffs assert that objective reasonableness is a question of fact, and that "contradictions regarding whether the 'predicate facts' of the underlying litigation evidence probable cause are properly resolved by the jury." (D.I. 622 at 3 (citing *In re Relafen Antitrust Litig.*, 346 F. Supp. 2d 349, 360-61 (D. Mass. 2004) (additional citation omitted) (Teva)) That is, the court must still consider the record in the light most favorable to plaintiffs, without resolving facts or weighing evidence regardless of what burden of persuasion applies. (Civ. No. 03-130, D.I. 531 at 19 (Impax))

According to defendants, "[t]he question presented by this motion is, in effect, the inverse of [a] typical summary judgment motion in a patent case," insofar as "a finding that there are legitimate, disputed issues regarding infringement, invalidity or enforceability compels the grant of summary judgment in favor of defendants because such a finding necessarily means that defendants' litigations against Teva and Impax were not 'so baseless that no reasonable litigant could realistically expect to secure favorable relief' as required by [*Professional Real Estate*]." (Civ. No. 05-360, D.I. 389 at 5)

Neither party is essentially incorrect. With respect to plaintiffs' sham litigation claims based on inequitable conduct, the court may not resolve facts regarding Mr. Reginault's state of mind. It may, however, consider the circumstantial evidence regarding Mr. Reginault's state of mind without reaching the ultimate issue of intent. The existence of evidence which could amount to clear and convincing evidence of objective baselessness precludes summary judgment in favor of defendants. Put another way, defendants are correct that evidence tending to demonstrate that their infringement allegations had a reasonable basis mandates the grant of summary judgment in their favor.

has now been discovered that the co-micronization of fenofibrate and a solid surfactant (*i.e., the micronization of an intimate mixture of fenofibrate and a solid surfactant*) make it possible to improve the bioavailability of the fenofibrate . . . ." ('726 patent, col. 1, ll. 35-39) (emphasis added) Because Teva pre-micronized fenofibrate by itself, then added to this dry mixture a solution of dissolved SLS and water, defendants could only prove infringement by demonstrating that co-micronizing occurred during the later granulation process, which necessarily included fenofibrate, SLS and water. Similarly, Impax pre-micronized fenofibrate by itself prior to the addition of other excipients and a liquid surfactant. Notwithstanding the definition in the specification, defendants asserted that "co-micronized" should be construed to mean "micronized with or together," in accordance with the standard dictionary definition, such that other excipients (in addition to the fenofibrate and solid surfactant) would not be excluded from the claim's scope. Defendants maintained this position despite the fact that the specification never once described micronizing fenofibrate and solid surfactant with any other excipient. Defendants also relied on Dr. Goldberg's testimony that "intimate" has no usual meaning in the art; as per a dictionary, "intimate" can mean more than two items: "I can have an intimate conversation with my wife and child, that's not private, that's three of us." (Civ. No. 05-360, D.I. 406, ex. C at 177-178)

In support of the reasonableness of its position, defendants rely on Federal Circuit caselaw stating that "[i]t has long been recognized that . . . dictionaries . . . are particularly useful resources" in claim construction. (Civ. No. 05-360, D.I. 389 at 13 (citing *Texas Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202 (Fed. Cir. 2002)). The *Texas Digital* case, however, recognized that "the specification [may use] the

words in a manner clearly inconsistent with the ordinary meaning reflected, for example in a dictionary definition . . . the presumption in favor of a dictionary definition will be overcome where the patentee, acting as his or her own lexicographer, has clearly set forth an explicit definition of the term different from its ordinary meaning." *Id.* at 1204 (citations omitted). The Federal Circuit, in its 2005 *Philips v. AWH Corporation* decision, later cautioned against an over-reliance upon dictionary definitions in claim construction, but confirmed that, even under the *Texas Digital* line of cases, "an explicit definition of the term" in the specification would control.[35] 415 F.3d 1303, 1320 (Fed. Cir. 2005). Therefore, it is not the case where Federal Circuit caselaw was "in flux" or "fraught with uncertainty," as defendants suggest, when the capsule lawsuits were initiated. (Civ. No. 05-360, D.I. 389 at 14)

The Federal Circuit found that it was "abundantly clear" that defendants' construction was incorrect. *Abbott II*, 323 F.3d at 1330. The inclusion of the term "intimate" in the definition did not create ambiguity, rather, this term, "together with the fact that fenofibrate and SLS are the only ingredients present in every co-micronized mixture described in the '726 patent's specification, makes it abundantly clear that [the limitation] should be construed as referring to co-micronization of a mixture consisting essentially of fenofibrate and solid surfactant [not excluding the possibility of minor impurities.]" *Abbott II*, 323 F.3d at 1330. Not one court reviewing defendants' construction found it tenable, nor does this court. Defendants' assertions exceeded all

---

[35]The *Philips* court expressed concern for the methodology of using the specification only as a "check" on the dictionary definition in cases where terms were not expressly defined in the specification – circumstances not present in the capsule litigation. 415 F.3d at 1320.

reasonable interpretations of the major tenets of claim construction. The testimony of defendants' paid expert does not alter this conclusion.

Moreover, even notwithstanding, there is no credible argument that dissolved SLS could possibly be a "solid surfactant" as required by the claims. *Id.* at 1331. Neither Teva nor Impax had a manufacturing step where there was a mixture of only fenofibrate and a solid surfactant, and this was not unbeknownst to defendants.

Based upon the foregoing, the court finds that a jury could find defendants' infringement allegations objectively baseless, such as to render the capsule litigation a sham. The court denies defendants' motion on this ground.

b. Tablet litigation

In the tablet litigation, defendants "won" claim construction on the majority of disputed terms; nevertheless, summary judgment was granted against them. The court found that the excipients used by Impax (HPMC and MCC) were not "hydrophilic polymers" as required by the claims, or "any high molecular weight substance (greater, for example, than 300) having sufficient affinity towards water to dissolve therein and form a gel." (Civ. No. 03-120, D.I. 245 at 15-17)

For this limitation, the court adopted the construction as proposed by Teva and Impax. (*Id.*, D.I. 245 at 13-14) Again, this was a situation where the patentees acted as their own lexicographers, stating in the specification that "[t]he expression 'hydrophilic polymer' in the invention should be taken to mean any high molecular weight substance (greater, for example, than 300) having sufficient affinity towards water to dissolve therein and form a gel." ('670 patent, col. 4, ll. 14-17) Defendants asserted that this express definition purportedly conflicted with a passage in the

specification stating that, "[d]epending on polymer solubility, [the hydrophilic polymer either dissolves in the solution or forms a gel or a suspension having various degrees of thickness." (*Id.*, col. 6, ll. 25-27) The court disagreed, noting that the paragraph cited by defendants, taken its entirety,[36] makes clear that the solvent can be aqueous or organic. (Civ. No. 03-120, D.I. 245 at 16) If the suspension contained an aqueous solvent, the polymer would dissolve or form a gel, but if the suspension contained an organic solvent, it would do one or the other. "Counsel for Abbott . . . was unable to articulate for the court why the statement '[t]he solvent employed can be aqueous or organic' does not relieve any perceived inconsistency in the use of the term hydrophilic polymer." (*Id.* at 16-17)

Applying this construction at the summary judgment stage, the court stated: "Abbott does not, and cannot, dispute Impax's assertion that under this construction, MCC is not a 'hydrophilic polymer,' because MCC does not dissolve in water[.]" (*Id.*, D.I. 257 at 25) HPMC does dissolve in water and otherwise would satisfy this limitation

---

[36]Specifically,

> [t]he significant starting product is the suspension of the active ingredient. This suspension is prepared by putting the micronized active ingredient into suspension in a solution comprising the hydrophilic polymer and, optionally, a surfactant, in solution in a solvent. If a surfactant is employed, it is put into solution in the solvent (beaker + magnetic or vane stirrer). Next, the hydrophilic polymer (PVP) is dispersed, while stirring, in the solution previously obtained. *Depending on polymer solubility, this either dissolves in the solution or forms a gel or a suspension* having varying degrees of thickness. While still stirring, the micronized active ingredient is dispersed in the form of a fine shower into the above solution or suspension, to form a homogeneous suspension. The order of these steps can be reversed. *The solvent employed can be aqueous or organic* (for example ethanol). For example demineralized water can be used.

('670 patent, col. 6, ll. 16-32) (emphasis added)

but, because it was undisputed that HMPC comprised only 2% by weight of Impax's product, Impax could not infringe any of the asserted claims requiring a "hydrophilic polymer" of at least 20% by weight.[37] (*Id.*)

For similar reasons to those noted above with respect to the capsule litigation, the court denies defendants' motion for summary judgment of no sham litigation on this ground insofar as a jury could find defendants' infringement allegations objectively baseless. Once again, defendants' claim construction arguments were untenable in the tablet litigation, contradicting the express definition provided in the specification, and exceeding all reasonable interpretations of the major tenets of claim construction. Defendants were unable to justify their strained interpretation when called upon to do so by the court. Under the patentees' own given definition, defendants could not plausibly assert that MCC, which is insoluble in water, was "hydrophilic"; there never seemed to be any doubt that Impax did not use enough HMPC to meet the weight percent limitation.

After extensive litigation, defendants dropped the remainder of their infringement claims a month prior to trial, and executed a covenant not to sue. Having deprived the court of the opportunity to flesh out the merits of the remainder of its claims, the court declines to afford defendants the benefit of the doubt that its claims were reasonable. However, the court does note, in accordance with the summary judgment standard, that a jury could find the remainder of defendants' infringement claims (hinged upon the "hydrosoluble carrier" limitation) are objectively baseless. Defendants claimed that Ac-

[37]Claim 9 of the '409 patent and claims 1-8, 11, 25, 27 and 56 of the '552 patent.

Di-Sol®, despite swelling upon contact with water causing the tablet to break into pieces, functions in the same "way" as a hydrosoluble carrier (one that dissolves in water, releasing the fenofibrate). On its face, defendants' argument is nonsensical.[38] Moreover, defendants' own documents demonstrate an appreciation for this fact. (D.I. 625 at TIJA-2271.1) ("Replacing the water-soluble excipient by a non-water-soluble excipient is actually beyond the scope of the PharmaPass patent.") Based upon the foregoing, summary judgment is inappropriate.

2. *Walker-Process* fraud and unenforceability

Plaintiffs assert that the data submitted to the PTO, and contained in Figure 1 of the '881 patent, is false. Plaintiffs do not directly challenge the methodologies utilized to obtain the purportedly inaccurate data. Rather, plaintiffs seek to demonstrate the falsity of the reported data through comparison to the dissolution data obtained by Blouquin in 1997.[39]

---

[38]The testimony of defendants' expert, Dr. James McGinity, does not alter this fact. Dr. McGinity opined that the "way" is equivalent because, despite being hydrophilic, Ac-Di-Sol® "facilitat[es] wetting of the micronized fenofibrate" by swelling and breaking the tablet apart, exposing additional surface area of the fenofibrate. (Civ. No. 05-360, D.I. 392 at DJA-936) Defendants also cite the testimony of its expert Dr. Byrn, but its citations do not correspond to Dr. Byrn's report. (*Id.*, D.I. 389 at 28, citing D.I. 392 at DJA-508-23) Essentially, and notwithstanding that its hired experts have agreed with them, defendants claim that a carrier that dissolves in water functions in the same way as one that does not dissolve in water – an argument the court finds implausible.

[39]To be clear, plaintiffs do not specifically state whether their unenforceability arguments center around the Tricor® 67 mg data found in the Developmental Report in addition to the Blouquin data. Impax describes both sets of withheld data in the background section of its responsive paper, followed by references to the "Fournier testing results" and the like in the argument. (Civ. No. 03-120, D.I. 531) Teva's responsive paper, however, indicates that plaintiffs focus only on the Blouquin data. (D.I. 622 at 31 ("Plaintiffs focus . . . on 1997-1998 – when Fournier prepared and filed

Defendants do not specifically contest that the withheld data contradicts statements later made in support of the patentability of '881 patent. (D.I. 634 at 10-11 (consolidated reply)) Notwithstanding, the fact that there were inconsistent test results that might have been of interest to an examiner does not prove that any particular test results were actually false, as test results can differ from day-to-day. Plaintiffs do not contest defendants' representation that hundreds of dissolution tests were performed. (D.I. 389 at 30) That one or two specific tests yielded results contradictory to those claimed is insufficient evidence upon which to draw the conclusion that the test data submitted to the PTO was objectively false.[40] For these reasons, the court grants defendants' summary judgment motion on plaintiffs' *Walker-Process* claims.

With respect to their sham litigation claims, plaintiffs assert that summary judgment should be denied insofar as there is sufficient basis for a jury to conclude that Mr. Reginault intentionally withheld the highly material[41] Blouquin and Developmental Report data from the PTO with an intent to deceive, and that Fournier asserted the Stamm patents while knowing of this unenforceability. (Civ. No. 03-130, D.I. 531 at 36-

---

the first U.S. patent application.")) The court will assess plaintiffs' arguments with respect to both inconsistent test results.

[40]The court's conclusion is unaffected by the inclusion of the Tricor® 67 mg data contained in the 2000 Developmental Report; in other words, against a backdrop of hundreds of tests, two inconsistent test results are insufficient to demonstrate the falsity of the data submitted to the PTO. Presumably, plaintiffs would highlight any additional Fournier data conflicting with the '881 patent or statements made in furtherance of the patentability of the '881 patent; there is no indication that any of the other hundreds of tests were in conflict.

[41]Defendants do not contest the materiality of the data contained in the Blouquin memo. (D.I. 634)

37)

Plaintiffs' inequitable conduct theory requires a demonstration that Mr. Reginault had a duty of candor to the PTO, and violated that duty by intentionally withholding the Blouquin 1997 test data. Mr. Reginault undoubtably became "substantively involved in the preparation or prosecution of the application" in 2003 when he submitted his technical declaration to the PTO. 37 C.F.R. § 1.56©. Prior to this point, however, there is little indication that Mr. Reginault owed a duty of disclosure.

Teva asserts that Mr. Reginault was substantively involved in the prosecution of the '881 patent prior to 2003, insofar as: (1) "at least two of his ideas were included in the patent application" (the use of 0.025 M SLS and co-micronized fenofibrate); (2) Mr. Reginault worked with the people in the patent division of Fournier's legal department regarding fenofibrate patents; and (3) "Reginault's knowledge of the technology and role in licensing it from PharmaPass, by itself, is 'substantive involvement.'" (D.I. 622 at 23-24)

Teva first claims that defendants have offered no explanation for how the use of 0.025 M SLS and co-micronized fenofibrate was inserted into the '128 application (appearing, thereafter, in the other Stamm patents); insofar as these were Mr. Reginault's ideas, "[t]he inclusion of [these] ideas in the patent itself demonstrates his substantive involvement." (D.I. 622 at 24) The court disagrees. The lack of evidence regarding the drafting of the '128 patent application is not evidence in support of plaintiffs' theory, nor does it demonstrate that it was Mr. Reginault who suggested this information be included. In contrast, there are facts of record tending to point away from Mr. Reginault. Dr. Stamm testified that he and Dr. Seth, both named inventors,

used 0.025 M SLS in their testing at PharmaPass. (D.I. 303, pt. 2 at 35-38) In addition, the French priority application disclosed the use of a co-micronized active ingredient, and claimed a composition where the "active ingredient and the surfactant are co-micronized." (D.I. 625 at TIJA-2250, TIJA-2240 ("When a surfactant is present, the active ingredient can be co-micronized with the surfactant.")) Teva's theory is, at best, speculative.

Mr. Reginault's testimony regarding his involvement with the patent department is equally uncompelling. As an initial matter, Mr. Reginault was involved with the patent department (and, generally, "fenofibrate patents") at Fournier because he was a named inventor of the '726 patent. There is no evidence of record regarding what the "audit" of patents in 2001, in which Mr. Reginault participated, entailed; it is possible that Mr. Reginault's involvement was limited to matters concerning the '726 patent. (D.I. 626 at TIJA-3222) With respect to the Stamm patents, Teva points only to Mr. Reginault's testimony regarding a single conversation, in which Mr. Reginault discussed a fenofibrate product.[42] (D.I. 626 at TIJA-2049) (stating that he "explained the [fenofibrate] product to them, explained what the formulation was and did so in simple terms for someone who was not familiar with it."))

Finally, Mr. Reginault's knowledge of the technology and role in licensing it from

---

[42]In *Avid Identification Systems, Inc. v. Phillips Electronics N.A.*, Civ. No. 04-183, 2007 WL 2901514 (E.D. Tex. 2007), cited by Teva (D.I. 622 at 26-27), the court found that a co-founder and CEO of a company owed a duty of candor to the PTO in view of evidence that: (1) an inventor sent him a fax regarding checking with patent attorneys regarding whether public sales could invalidate a European patent; and (2) correspondance from an inventor enclosing "new material for the patent application." *Avid*, 2007 WL 2901514 at *3-4. No comparable evidence exists in this case.

PharmaPass is not, as Teva asserts, "substantive involvement" in the preparation or prosecution of any of the applications leading to the Stamm patents. On this point, Teva cites *Kemin Foods, L.C. v. Pigmentos Vegetables del Centro S.A. de C.V.*, 357 F. Supp. 2d 1105 (S.D. Iowa 2005), in which plaintiff's corporate president, "qualified in the science of the patent-in-suit [ ] and [who] negotiated with the '714 patent inventor to prosecute, obtain, and license the patent," was found by a jury to have had the requisite intent to deceive.[43] *Id.* at 1119. There is no indication that Mr. Reginault participated in the prosecution of the Stamm patents prior to the 2003 declaration.[44] Mr. Reginault testified that he did not see the French priority application, and did not see any of the applications leading to the Stamm patents until the time of his 2003 declaration. (D.I. 637 at DJA-Reply-11-12, 14) He received a graph of data that eventually was included as Figure 2 in the '182 application and the following Stamm patent applications; there is

---

[43]The *Kemin* court found that the jury's advisory finding that Kemin had an intent to deceive was supported, despite circumstances "suggest[ing] the conclusion [was] reached on a shallow basis." 357 F. Supp. 2d at 1120. The *Kemin Foods* court ultimately found the patent at issue enforceable.

[44]The court notes at this juncture that no one has clearly delineated the nature of the parties' involvement in the various patent prosecutions. The French patent (No. FR2758459) issuing from the French priority application appears to list PharmaPass as the applicant ("demandeur") and no assignee ("titulaire"). In contrast, the Stamm patents each list Fournier as the assignee. It is unclear which company, and on what continent, the various applications were prepared. Mr. Stamm is associated with PharmaPass in France, while Mr. Seth is listed as a resident of California.

Presumably, if plaintiffs had any direct evidence indicating Mr. Reginault's direct involvement in the prosecution of the Stamm patents, whether prepared and/or prosecuted at Fournier or not, plaintiffs' papers would essentially scream it out. Rather, plaintiffs rely on certain facts – that Mr. Reginault was involved with the prosecution of the '726 patent (as an inventor), an "audit" of patents in 2001, and discussed patents with PharmaPass – to create an implication that he must have been involved in the prosecution of the '881 patent (beyond the 2003 declaration). (D.I. 622 at 25-27) Plaintiffs' evidence falls short.

no evidence, however, that its inclusion had anything to do with Mr. Reginault.

In view of the foregoing, the relevant inquiry is whether plaintiffs can demonstrate that Mr. Reginault had, at the time he became involved in the prosecution of the '881 patent in 2003, an intent to deceive the PTO by withholding the 1997 Blouquin memo data and Developmental Report data. "[T]o intend to deceive the PTO about an omitted fact he had to know it." *Cargill, Inc. v. Canbra Foods, Ltd.*, No. Civ. A. 03-1209, 2005 WL 3478178, *2 (D. Or. Dec. 20, 2005). In his post-litigation 2005 declaration, Mr. Reginault denies recalling the omitted test data when he filed his declaration with the PTO in 2003. Plaintiffs attack the credibility of this after-the-fact declaration. (D.I. 622 at 28-29) Plaintiffs also assert that a myriad of evidence exists from which a jury could find that Mr. Reginault was aware of, and did recall, the Blouquin memo data in 2003, such as: (1) his focus on the patentability of the PharmaPass formulation; (2) the data was gathered at Mr. Reginault's request in the search for a dissolution medium that would demonstrate the difference in the tablet and capsule formulations; (3) Mr. Reginault received the Blouquin memo in 1997; and (4) he included the Blouquin data in the Developmental Report in 2000. (Civ. No. 03-120, D.I. 531 at 33-34)

Six years elapsed between the Blouquin memo and Mr. Reginault's 2003 declaration; three years elapsed between the Developmental Report and the 2003 declaration. Defendants state in their opening brief, and plaintiffs do not dispute, that "literally hundreds of dissolution tests" were performed during this time period. (Civ. No. 05-360, D.I. 389 at 30) The only indication that the Blouquin data specifically, the result of one of these hundreds of tests, was recalled thereafter by Mr. Reginault was his inclusion of the data in the Developmental Report – a 72 page document containing a

plethora of data, including at least six additional dissolution profiles. (D.I. 625 at TIJA-2128-30) There are no facts of record that could demonstrate that, notwithstanding the appearance of the two inconsistent data sets in the Developmental Report, Mr. Blouquin recalled, and intentionally withheld, this data three years later.

As discussed previously, the court does not resolve facts regarding Mr. Reginault's state of mind. However, weighing the circumstantial evidence of record, the court finds plaintiffs can not, on the evidence of record, meet their "clear and convincing" burden regarding Mr. Reginault's knowledge and intent. Absent clear and convincing evidence of inequitable conduct, plaintiffs can not demonstrate that defendants asserted the '881 patent while knowing of its unenforceability, so as to constitute sham litigation. Put another way, since defendants' position that Mr. Reginault did not violate any duty of candor to the PTO is not unreasonable, summary judgment must be granted on plaintiffs' sham litigation claims premised on inequitable conduct.

IV. CONCLUSION

For the aforementioned reasons, the court grants defendants' motion with respect to plaintiffs' sham litigation claims premised on inequitable conduct and plaintiffs' *Walker Process* claims, and denies defendants' motion with respect to plaintiffs' sham litigation claims based on a lack of probable cause for asserting patent infringement.[45] An appropriate order shall issue.

---

[45]The parties have not delineated which of plaintiffs' claims are litigation-based, i.e., "petitioning activity" for the purposes of its sham litigation claims. The parties' pre-trial submissions should reflect which of plaintiffs' claims remain triable, with reference to specific paragraphs of the complaints.